Art Unit: 1624

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicants:** Kenneth L. Arrington et al.

**Serial No.:** 10/582,826 **Case No.:** 21596P

**Filed:** June 14, 2006

For: MITOTIC KINESIN INHIBITORS Examiner: D. R. Rao

Mail Stop: Patent Ext. Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Sir:

With reference to the Issue Notification mailed November 11, 2009 the Applicants respectfully request reconsideration of the Patent Term Adjustment for this application under 35 U.S.C. § 154(b).

This Request for Reconsideration of Patent Term Adjustment is being submitted by EFS on December 09, 2009, within 2 months of the issuance of this application as US Patent 7,625,912 on December 01, 2009, and is accompanied by the fee set forth in 37 C.F.R. § 1.705(b)(1) and § 1.18(e). Any additional fees associated with this Request may be charged to Merck Deposit Account No. 13-2755.

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## **REMARKS**

The Issue Notification mailed November 11, 2009, indicated that the total patent term adjustment calculated by the Patent Office for this application is <u>565</u> days. Applicants hereby respectfully request reconsideration of the patent term adjustment for this application. Specifically, Applicants believe that the total patent term adjustment should be <u>730</u> days.

In support of this request, Applicants submit the following statement of facts pursuant to 37 C.F.R. § 1.705(b).

## REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

#### "A Delay"

The Office indicated that the patent term adjustment under 37 C.F.R. § 1.702(a) as calculated under 37 C.F.R. § 1.703(a) is <u>565</u> days. The beginning of the relevant period for purposes of calculating "A Delay" is the date on which the application fulfilled the requirements of 35 USC 371. This US national stage application fulfilled the requirements of 35 USC 371 on June 19, 2006.

A first PTO action was due on or before August 19, 2007 (the date that is fourteen months after the date that the US national stage application fulfilled the requirements of 35 USC 371 on June 19, 2006). The PTO mailed the first Office Action on March 06, 2009, thereby according a PTO Delay of **565** days.

Applicants agree with the determination by the Office that the patent term adjustment under 37 C.F.R. § 1.702(a) as calculated under 37 C.F.R. § 1.703(a) is **565** days.

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## "B Delay"

Applicants respectfully submit that the patent term adjustment under 37 C.F.R. § 1.702(b) as calculated under 37 C.F.R. § 1.703(b) is **165** days.

The beginning of the relevant period for purposes of calculating "B Delay" is the date on which the application was commenced under the provisions of 35 USC 371(b). The US national stage for this application was commenced on June 19, 2006.

US Patent 7,625,912 granted from the subject application on December 01, 2009. The US national stage for this application was commenced on June 19, 2006. Accordingly, the application should have issued within three years later, on June 19, 2009. However, the actual issue date was December 01, 2009. The difference between the date when the application should have issued to patent on June 19, 2009, and the date that the application actually issued to patent on December 01, 2009, is **165** days.

## Overlap of "A Delay" and "B Delay"

As detailed above, "A Delay" accumulated during the following period: June 19, 2006 to August 19, 2007

As detailed above, "B Delay" accumulated during the following period: June 19, 2009 to December 01, 2009

The "A Delay" and the "B Delay" overlap (i.e. occur on the same calendar day) for a total of **0** days.

The adjustment sought under 37 C.F.R.§ 1.703(f) is the sum of the periods under § 1.702(a) ( $\underline{565}$  days) and § 1.702(b) ( $\underline{165}$  days), less the additional delays attributable to Applicant ( $\underline{\mathbf{0}}$  days), less the days that such periods overlap ( $\underline{\mathbf{0}}$  days). Accordingly, Applicants respectfully request an adjustment of patent term under § 1.703(f) to indicate a total Patent Term Adjustment of  $\underline{730}$  days.

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In support of Applicants' request for the adjustment under § 1.703(f) to include the sum of the periods under 1.702(a) and § 1.702(b), rather than the greater of these two periods, Applicants rely on the decision of the U.S. District Court for the District of Columbia in *Wyeth v. Dudas*, Civil Action No. 07-1492 (D.D.C. September 20, 2008). In that decision, the Court construed the meaning of the statutory provision regarding the limitations on extensions granted for delays under 35 U.S.C. § 154(b)(1)(A-C):

(A) In general. -- To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). The court stated that "[t]he operative question under 35 U.S.C. § 154(b)(2)(A) is whether periods of delay attributable to grounds specified in paragraph (1) overlap." See Memorandum Opinion at p. 8. (internal quotations omitted). In the opinion of the district court, "[t]he only way that periods of time can "overlap" is if they occur on the same day." Id. The court thus rejected the Patent Office's view that any administrative delay under 35 U.S.C. § 154(b)(1)(A) ("A delays") overlaps with any 3-year maximum pendency delay under 35 U.S.C. § 154(b)(1)(B) ("B delay"). In the district court's view, the only A delays which overlap with the B delay are those which occur after the B period begins, which is when the Patent Office has failed to issue a patent within three years of an application's filing date, and not before. See Memorandum Opinion at p. 5-6, 9.

Applying the rule in Dudas to the present facts, the period for A delays ends on June 19, 2009, which is three years from the filing date of this application, June 19, 2006. The period for B delay begins on June 19, 2009, and ends on the date of issuance of the patent on December 01, 2009, a period of  $\underline{165}$  days inclusive. Accordingly, the total patent term adjustment should be calculated from the sum of the non-overlapping A and B periods  $\underline{565} + \underline{165} - \underline{0}$  days, less the delays due to applicant during the B period,  $\underline{0}$  days, giving a total of  $\underline{730}$  days.

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## Terminal Disclaimer

Applicants note that the above-identified application is not subject to a terminal disclaimer.

## **Applicant Delay**

There was no Applicant delay.

In that the decision of the U.S. District Court for the District of Columbia in *Wyeth v. Dudas* is under appeal to the Court of Appeals for the Federal Circuit, Applicants respectfully request that any decision on this request for reconsideration of the patent term adjustment be held in abeyance until a final court decision in *Wyeth v. Dudas* is rendered.

In summary, Applicants respectfully requests an adjustment of patent term under 37 C.F.R § 1.703(f) to indicate a total PTA of <u>730</u> days. Favorable consideration of this request is earnestly solicited.

Respectfully submitted,

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